K080876

510(k) Summary

JUN - 4 2008

Submitted on behalf of:

BK MEDITECH Co., Ltd.
215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si,
Kyunggi-Do, Republic of Korea

by: **Elaine Duncan, M.S.M.E., RAC**
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
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CONTACT PERSON:	**Elaine Duncan**
DATE PREPARED:	**March 28, 2008; revised May 28, 2008**
TRADE NAME:	**DVX Spinal System**
COMMON NAME:	Spinal System, Fusion
CLASSIFICATION NAME:	Posterior Spinal Fusion System with solid rod and pedicle screws
REGULATION and CLASS	21 CFR § 888.3070, Class 2
PANEL and PRO CODE:	Orthopedic; MNH

SUBSTANTIALLY EQUIVALENT TO: The DVX Spine System, is substantially equivalent to the NFix Fusion System cleared for market by N Spine, Inc. under K053623, and to MEGA Spine System (K072436) for the cross-link member. The DVX Spine System is equivalent to the N Spine system and the MEGA Spine cross-link member with respect to materials, design, indications for use, operational principles and source manufacturer. There are no substantial differences between the subject devices and the predicate devices and thus no differences which could affect safety or efficacy.

DESCRIPTION of the DEVICE: The DVX Spine System consists of four or more pedicle screws and two DVX solid rods in a symmetric, bilateral arrangement. The pedicle screws are placed axially in the pedicles with two screws in the cephalad position and two screws in the caudad position. The DVX rods are secured in the heads of the pedicle screws so that fixed stabilization is provided between the cephalad and caudad vertebrae. Cross-links can be used if additional stabilization is necessary. The DVX Spine System is fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to the ASTM F136 -02a, Standard Specifications for Wrought Titanium-6Aluminum-4VanadiumELI (Extra Low Interstitial) Alloy or Surgical Implant Applications (UNS R56401

INDICATIONS FOR USE: The DVX Spine System is intended for posterior, noncervical, pedicle fixation in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). In addition, when used as a pedicle screw fixation system, the DVX Spine System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 and below), with removal of the implants after the attainment of solid fusion.

BASIS for SUBSTANTIAL EQUIVALENCE: No additional testing is required because the test results applicable to the N SPINE System and MEGA spinal system components are directly applicable to the DVX Spine System since they are virtually identical in design and materials. Designs are directly compared to demonstrate equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

BK Meditech Co., LTD.
% Paladin Medical Inc.
Ms. Elaine Duncan
P.O. Box 560
Stillwater, MN 55082

Re: K080876
Trade/Device Name: DVX Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: March 28, 2008
Received: March 31, 2008

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080876

Device Name: **DVX Spine System**

The DVX Spine System is intended for posterior, noncervical, pedicle fixation in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the DVX Spine System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 and below), with removal of the implants after the attainment of solid fusion.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080876